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EXAMINER

NICKOL, GARY B

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 07/11/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/424,940

Applicant(s)

CRESS ET AL.

Examiner

Gary B. Nickol Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 22-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Response to Amendment***

The amendment filed 03-11-03 (Paper No. 16) in response to the letter mailed 12-19-02 (Paper No. 15) indicating errors with the raw sequence listing has been entered. Applicant's sequence listing is now in compliance. Thus, this action is in response to the following:

The Amendment filed January 18, 2002 (Paper No. 11) in response to the Office Action of June 19, 2001 is acknowledged and has been entered.

Claims 1-21 were cancelled.

Claims 22-27 were added.

Claims 22-27 are currently under consideration.

**The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.**

**NEW OBJECTIONS/REJECTIONS:**

***Claim Objections***

Claim 23 is objected to for reciting, "is performed using and enzyme-linked" as the word "and" is grammatically incorrect.

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Claim 27 is also objected to for reciting, "wherein in said biological sample" as the word "in" appears redundant.

***Claim Rejections - 35 USC § 112***

Claim 26 recites the limitation "said animal" in Claim 25. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

Claims 22, 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Wojtukiewicz *et al.* (Polish Jnl. Pharm., 1996, Vol. 48, pages 229-232) as further evidenced by US Patent No. 4,851,334 (Kudryk *et al.*, 25 July 1989).

The claims are drawn to a method for detecting cancer in a subject comprising contacting a biological sample obtained from said subject with a monoclonal antibody that binds to a fibrinogen degradation product (FDP) epitope of the beta chain of fibrinogen having an amino acid sequence corresponding to SEQ ID NO:1 and determining the presence or absence of said FDP, wherein fibrin, fibrinogen and fibrinogen fragments D and E are not detected (Claim 22); wherein said monoclonal antibody is generated using an immunogens prepared from a peptide having an amino acid sequence corresponding to SEQ ID NO:2 (Claim 24); wherein said subject is a human mammal (Claims 25-26).

Wojtukiewicz *et al.* teach a method for detecting cancer (gastric cancer) in human subjects comprising contacting a biological sample obtained from said subject with the

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monoclonal antibody T2G1 (page 230). As evidenced by US Patent No. 4,851,334, the mAB T2G1 is monospecific for a single determinant on the peptide fragment of the beta chain of human fibrin II containing amino acid residues 15-42 (column 5, line 63+). This encompasses a monoclonal antibody generated using an immunogen prepared from a peptide having an amino acid sequence corresponding to SEQ ID NO:2 and which binds to a fibrinogen degradation product (FDP) epitope of the beta chain of fibrinogen having an amino acid sequence corresponding to SEQ ID NO:1 because the specification teaches (page 12, line 18) that SEQ ID NO:2 (or GHRPLDKC) corresponds to amino acids 15-20 of the  $\beta$ -chain of human fibrinogen. Furthermore, US Patent No. 4,851,334 teaches (column 5, line 54) that fibrinogen and fibrin I are not detected. And, although, the reference does not specifically teach that fragments D and E are also not detected, the claimed method appears to be the same as taught in the prior art and would inherently not detect said fragments. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the method of the prior art does not possess the same material, structural and functional characteristics of the claimed method. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

***Claim Rejections - 35 USC § 103***

Claims 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wojtukiewicz *et al.* (Polish Jnl. Pharm., 1996, Vol. 48, pages 229-232) and US Patent No. 4,851,334 (Kudryk *et al.*, 25 July 1989).

Wojtukiewicz *et al.* teach as set forth above.

Wojtukiewicz *et al.* do not specifically teach using an enzyme-linked immunoadsorbent assay (ELISA) to detect a fibrinogen degradation product (Claim 23) or wherein said biological sample is selected from the group consisting of blood, serum, plasma, urine, cervical secretions, bronchial aspirates, sputum, saliva, feces, synovial fluid and cerebrospinal fluid (Claim 27).

US Patent No. 4,851,334 teaches methods of detecting fibrinogen degradation products in blood using ELISAs (columns 11-12), including employing monoclonal antibodies that recognize an epitope of the beta chain of fibrinogen having an amino acid sequence corresponding to SEQ ID NO:1.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modulate the method of Wojtukiewicz *et al.* so as to include the detection of a fibrinogen degradation product (FDP) epitope of the beta chain of fibrinogen having an amino acid sequence corresponding to SEQ ID NO:1 in blood using an ELISA because Wojtukiewicz *et al.* successfully teach an immunohistochemical method for detecting the presence of gastric cancer, and US Patent No. 4,851,334 teaches that the assays of the invention can be used to measure fibrin degradation products in a number of trauma patients, including cancer patients (column 14, line 42). Further, one would have been motivated to combine the teachings because Wojtukiewicz *et al.* teach that gastric cancer is associated with an increased

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risk of thrombosis (page 230, 1<sup>st</sup> line), and US Patent No. 4,851,334 teaches that predominant amounts of B $\beta$  15-42 (recognized by the Mab T2G1) over B $\beta$  1-42 may lead to occlusive thrombosis (column 14, line 15). Thus, based on the successful teachings of Woztukiewicz *et al.*, combined with the teachings of US Patent No. 4,851,334, one of ordinary skill in the art would have had a reasonable expectation of success that cancer would be detected by determining the presence or absence of such fibrin degradation products by employing a blood-based ELISA.

No claim is allowed.

**All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.**

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol Ph.D.  
Examiner  
Art Unit 1642

GBN  
July 7, 2003

  
ANTHONY C. CAPUTA  
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